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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,556	05/16/2007	Kentaro Nakamura	2870-0341PUS1	8157

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EXAMINER

GERIDO, DWAN A

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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01/09/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/589,556	Applicant(s) NAKAMURA ET AL.	
	Examiner Dwan A. Gerido, Ph.D.	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 8 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 7.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No.

11/060,775. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-7 recite nearly identical limitations (3 layers of an analysis

Art Unit: 1797

element) within the same device. Claim 1 of application 11/060,775 recites the parameters for mean deviation and irregularity profile of the contact surface whereas the instant claims are silent to a mean deviation/irregularity profile. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify application 10/589,556 in view of 11/060,775 as determining the parameters of a result effective variable requires only routine skill in the art.

4. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1797

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 2, and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagatomo et al., (US 5,023,052).

9. With regards to claim 1, Nagatomo et al., teach a multilayer analysis element comprising a functional layer, a porous liquid sample spreading layer, and a water impermeable support wherein the spreading layer is non-fibrous (abstract, column 5 lines 25-43, figures 1). Nagatomo et al., do not recite values bending rupture strength, tensile percentage, or tensile force. Bending rupture strength and tensile percentage at a given force represent inherent variables present in any multilayer analysis element; therefore, setting specific values for said variables is viewed as optimization of known parameters. In addition, the MPEP states that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (MPEP 2144.05 IIA). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Nagatomo et al., wherein a test element comprises a bending rupture strength of 20 gram-weight, a tensile percentage of 2 percent or less, and a tensile force of 50 gram-weight as discovering an optimum value of a result effective variable requires only routine skill in the art.

10. Claims 2, 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagatomo et al., (US 5,023,052).

Art Unit: 1797

11. With regards to claims 2, and 5-8, Nagatomo et al., teach a multilayer analysis element comprising a porous film of organic polymers, specifically polyamide, polyethylene, and polypropylene, 6-nylon, 6,6-nylon, and polysulfone (column 3 lines 32-34, column 4 lines 8-12).
12. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagatomo et al., (US 3,992,158) in view of Hildenbrand et al., (US 4,824,639).
13. With regards to claims 3 and 4, Nagatomo et al., do not teach an analysis element with an asymmetry ratio of 2 or more, nor do they teach a symmetry ratio less than 2.

Hildenbrand et al., teach a multilayer test strip comprising a microporous polymer layer with an asymmetric pore structure that is advantageous because it filters particles based on size. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Nagatomo et al., in view of Hildenbrand et al., to gain the advantage of utilizing an asymmetric pore structure in order to filter particulates within the sample material based on size. Nagatomo et al., in view of Hildenbrand et al., do not recite values for asymmetry or symmetry ratios. The asymmetry and symmetry ratios are being read as an inherent feature of any porous layer as the layer would exhibit both symmetry and/or asymmetry with regards to pores within the layer, and setting values for said ratios is viewed as optimization of known parameters. In addition, the MPEP states that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (MPEP 2144.05 IIA). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Nagatomo et al., in view of Hildenbrand et al., in order to control pore size by optimization of the symmetry/asymmetry ratios.

Response to Arguments

14. Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that the reference of Terashima et al., does not teach an analysis comprising a non-fibrous layer. Rejection of the instant claims as obvious over Terashima et al., has been removed, and a new grounds of rejection have been applied. Applicant also argues that bending rupture strength, tensile percentage, asymmetry ratio, and symmetry ratio are not matters of optimization within the analysis element. It is the examiners position that the listed parameters are present in all multilayer analysis elements and that it would have been obvious to one of ordinary skill to optimize specific parameters (rupture strength, tensile percentage, symmetry/asymmetry ratios) based on how the analysis element is utilized and the origin of the sample to be tested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797
DAG